REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 1-6 and 8-28 are now pending in this application.

Claim 7 has been canceled and claims 1, 5, 8, 10, 14-19, 21, 27 and 28 have been amended to more particularly point out and distinctly claim the invention.

The amendments to claim 1 indicating that the nucleic acid is a DNA sequence are supported in the original application such as at paragraph [0021] second line. The amendments indicating that the DNA sequence is chosen from a plasmid, a phagemid and a cosmid are supported at paragraph [0021] at lines 5-6. These portions of the specification also support the amendments made to the dependent claims and to independent claim 16 and independent claim 27.

The amendments to claim 27 are also supported as indicated above and made in response to formal objections raised by the Examiner. Further, additional support can be found within the original specification such as in paragraphs 22 and 23. Other claim amendments are believed to be formal in nature. No new matter has been added.

Claims 20 and 28 were objected to due to informalities. The Examiner is correct with respect to these objections and claims have been amended to overcome the informalities and thereby overcome the objections.

Rejections under 35 U.S.C. §112, second paragraph

Claims 5, 8, 10, 27 and 28 were rejected under 35 U.S.C. §112, second paragraph as being indefinite. The rejections are traversed as applied and as they might be applied as the presently pending claims.

The objection directed to claim 5 is not acquiesced to. However, applicants wish to expedite prosecution and have specifically amended the claim in order to include the specific language requested by the Examiner. It being understood that the term "protein" is not intended to be limited to naturally occurring proteins but rather to amino acid sequences which have a particular confirmation such that they have biological activity.

The specific language objected to has been deleted thereby overcoming this rejection.

The Examiner's objection to claim 10 appears to be correct and applicants have amended claim 10 to include the specific language suggested by the Examiner thereby overcoming the objection.

The amendments to claims 27 and 28 appear to be formal in nature. Applicants have attempted to amend the claims in order to include language such as that suggested by the Examiner in an attempt to overcome the objection. Should the Examiner wish to include different language applicants would be amenable to amending the claims to place them in proper form for allowance.

Rejection under 35 U.S.C. §102

Claims 1-5, 8, 10, 11, 13-18 and 25 were rejected under 35 U.S.C. §102 as anticipated by Douthart et al. as evidenced by Sugiura et al. The rejection is traversed as applied and as it might be applied to the presently pending claims.

Applicants point out that Douthart et al. is directed to the use of RNA sequences. These sequences are used in combination with tobramycin in order to simulate viral infection and thereby stimulate the production of interferon. Because there is an attempt to simulate a viral infection there would be no attempt to use DNA sequences. The present claims have been amended to specifically claim DNA sequences and specifically indicated what those DNA sequences might be.

The Sugiura et al. reference as apparently been cited in order to show that RNA has a high molecular weight polynucleotide. However, the claims have now been amended to eliminate RNA. In view of such the 35 U.S.C. §102 objections and rejections are believed to have been overcome.

Rejections under 35 U.S.C. §103

Claims 16, 19 and 26 were rejected under 35 U.S.C. §103 as unpatentable over Heyes et al. in view of U.S. Patent 4,400,375 to Douthart and to the Douthart et al. publication. The rejections are traversed as applied and as they might be applied to the presently pending claims.

Claim 16 has been amended similar to that of claim 1. Specifically, the term "nucleic acid" has been deleted and replaced with the term –DNA sequence—chosen from a plasmid, a phagemid and a cosmid. The Douthart et al. patent and publication are clearly directed toward RNA sequences which are necessary in order to simulate the viral infection and thereby stimulate the production of interferon. Hayes et al. has been cited for its teachings with respect to delivering RNA sequences. Thus, even if the references are combined they still do not teach applicants' invention and do not suggest such or render it obvious in that the references require RNA sequences and applicants' claims specifically exclude such. In view of such the rejection is believed to have been overcome and its reconsideration and withdrawal is respectfully requested.

Claims 1, 6 and 9 were rejected under 35 U.S.C. §103 as unpatentable over Heyes, Douthart (1983) and Douthart (1982) and Gonda et al. The rejection is traversed as applied and as it might be applied to the presently pending claims.

As indicated above the primary references do not disclose the combination of DNA sequences with a cationic aminoglycoside as claimed within amended claim 1. Further, the references require the use of RNA sequences. Gonda et al. does nothing more than teach inhalation in general and does not suggest the combination of DNA sequences with cationic aminoglycosides. In view of such the rejection is believed to have been overcome and its reconsideration and withdrawal is respectfully requested.

Claims 1, 12, 16, 19 and 20 were rejected under 35 U.S.C. §103 as unpatentable over the combination of Gautam et al. in view of Douthart (1983) and Douthart (1982) and U.S. Patent 5,789,245 to Dubensky et al. The rejection is traversed as applied and as it might be applied to the presently pending claims.

As pointed out above the primary references do not teach DNA sequences in combination with a cationic aminoglycoside. Absent this essential teaching it is not possible to combine the references in a manner which would suggest the presently claimed invention. In view of such reconsideration and withdrawal of the rejection is respectfully requested.

Claims 21-24, 27 and 28 were rejected over Gautam, Douthart (1983), Douthart (1982), Dubensky and Gonda et al. The rejection is traversed as applied and as it might be applied to the presently pending claims.

Applicants have discovered a unique combination of components in the form of a DNA sequence and a cationic aminoglycoside. When this combination of components is brought into contact with a cell the DNA sequence may be a plasmid, a phagemid or cosmid transfects the cells with a high degree of efficiency.

Although applicants do not acquiesce to the obviousness of the combination of references put forth within the rejection it is applicants' position that even if said combination of references provided a *prima facie* case of obviousness, such is overcome by the results obtained by applicants. Nothing within the cited references suggest that it would be possible to improve the efficiency of transfecting cells by combining DNA sequences and a cationic aminoglycoside. In view of such reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1 and 7 were rejected under 35 U.S.C. §103 as unpatentable over the combination of Boussif et al. in view of Douthart et al. (1983), Douthart et al. (1982) and Dubensky et al. The rejection is traversed as applied and as it might be applied against the presently pending claims. Applicants have now canceled claim 7 from the application. Currently, the claims are directed towards the combination of a particular group of DNA sequences with a cationic aminoglycoside. Such combination is not taught within the references as taken alone or in combination with each other in that this combination is not taught the results obtained from such would not be understood by those skilled in the art and the references do not render the invention obvious.

Conclusion

In response to the Office Action applicants have amended the claims to overcome informalities and specifically amended the independent claims to indicate that the nucleic acid is a DNA sequence chosen from a plasmid, a phagemid and a cosmid. The combination of such a DNA sequence with a cationic aminoglycoside is not taught within the cited references as taken alone or in combination with each other. Applicants have obtained improved unexpected results with this combination in terms of increasing the efficiency of cell transfection. In that such results are not suggested within the references it is applicants' position that it would not be obvious to combine the references in any manner so as to obtain applicants' invention. In view of such reconsideration and withdrawal of the rejection is respectfully requested.

Applicants would be amendable to amendments to the claims that might be suggested by the Examiner to put the application in condition for allowance. In the event minor amendments are believed to be necessary applicants respectfully request an interview in order to expedite prosecution and place the application in condition for allowance.

In the event any fees are due in connection with this document or additional fees and petitions are required applicants petition for any additional required relief and authorize the Commissioner to charge the costs of any petitions to our Deposit Account No. 50-0815.

Respectfully submitted,
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Date: 3/FEB/04

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